

**MAY 21 2003**

F: 510(k) Summary

K 0 31082

March 31, 2003

Company: Gyrus Medical, Inc.  
6655Wedgwood Road  
Maple Grove, MN  
55311-3602  
Tel. No. (763) 416-3000  
FAX. No. (763) 416-3070

Contact: Mercedes Bayani  
Director, Regulatory Affairs

Common/Usual Name: Electrosurgical Instruments

Classification Name: Electrosurgical Cutting and Coagulation Device  
and Accessories (21 CFR 878.4400)

Proprietary Name: Everest Bipolar L Hook and Gyrus Bipolar L Hook

The device is a Class II medical device. The Bipolar L Hook is a modification to the predicate device cleared under K904993. The Bipolar L Hook is identical in construction (with the exception of shaft length) and in component materials when compared to the predicate device. The forceps jaws are electrically isolated from each other enabling one jaw to act as a return electrode, eliminating the need for a return pad. The modification has not altered the fundamental technology of the predicate device cleared under K904993. The intended use, electrosurgical coagulation, grasping and dissection of the tissue during surgical procedures is similar to the predicate devices cleared under K904993. The energy source, bipolar electrosurgical energy, is the same energy type as used for the predicate devices.

In conclusion, as the design, materials of construction, function and intended use of the modified Bipolar L Hook is similar to that of the predicate devices currently cleared, Gyrus Medical Inc. believes that no new issues of safety and effectiveness are raised and that the submitted device is substantially equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**MAY 21 2003**

Ms. Mercedes Bayani  
Director, Regulatory Affairs  
Gyrus Medical, Inc.  
6655 Wedgwood Road  
Maple Grove, Minnesota 55311

Re: K031082

Trade/Device Name: Everest Bipolar L Hook and Gyrus Bipolar L Hook  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical cutting and coagulation device and accessories  
Regulatory Class: II  
Product Code: GEI  
Dated: March 31, 2003  
Received: April 24, 2003

Dear Ms. Bayani:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

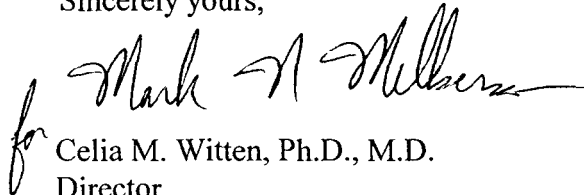
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

for Mark N. Milburn

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K031082

Device Name: Everest Bipolar L Hook & Gyrus Bipolar L Hook

Indications for Use:

Electrosurgical coagulation, electrosurgical cutting, dissection of tissue, irrigation and aspiration during the performance of laparoscopic and general surgical procedures.

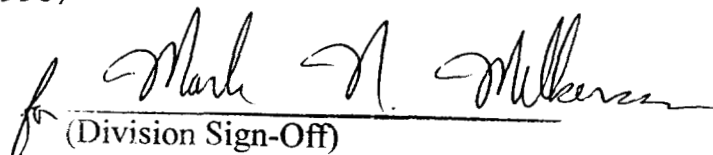
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OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Posted July 1, 1998)



(Division Sign-Off)

Division of General, Restorative  
and Neurological Devices

510(k) Number K031082